



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/520,962

11/28/2005

Naomi Burke Anker

MS0012YP

4932

210 7590 06/30/2008
MERCK AND CO., INC
P O BOX 2000
RAHWAY, NJ 07065-0907

EXAMINER

OLSON, ERIC

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

06/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,962	Applicant(s) ANKER ET AL.	
	Examiner Eric S. Olson	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 14, 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 5-24 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 and 25 is/are allowed.
- 6) ☒ Claim(s) 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

This office action is a response to applicant's amendment and arguments submitted February 14, 2008 wherein claims 1, 4, 8-11, 13, 15-23, and 26 are amended. This application is a national stage application of PCT/US03/21493, filed July 8, 2003, which claims benefit of provisional application 60/394734, filed July 11, 2002.

Claims 1-26 pending in this application.

Claims 4, 25, and 26 as amended are examined on the merits herein.

Applicant's amendment, submitted February 14, 2008, with respect to the rejection of instant claim 26 under 35 USC 112, second paragraph for an indefinite reference to a C₀ alkyl, has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to indicate that a C₀ alkyl is the absence of an alkyl group, namely a hydrogen. Therefore the rejection is withdrawn.

Applicant's amendment, submitted February 14, 2008, with respect to the rejection of instant claim 4 under 35 USC 112, second paragraph for omitting a description of who the compound is administered to, has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to recite administering the compound to a patient in need thereof. Therefore the rejection is withdrawn.

Applicant's amendment, submitted February 14, 2008, with respect to the rejection of withdrawn claims 8-24 under 35 USC 112, first paragraph for lacking enablement for preventative methods, has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to no longer encompass preventative methods. Therefore the rejection is withdrawn.

The following grounds of rejection of record in the previous office action are maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Uchida et al.
(Reference of record in previous action)

Uchida et al. discloses the synthesis of pyrrolo-pyridazines by condensation of a pyrrole-diketone (all compounds **6** and **7**) with hydrazine. (p. 241, right column, last paragraph, p. 244, left column, first paragraph) Products synthesized in this manner include compounds 10(a-c) which fall within the limits of instant claim 26. (p. 244, left column, top of column, compound **10**) Furthermore, the compounds **6** and **7** as shown on p. 241, right column, top of column, include additional embodiments of **10** wherein R¹

Art Unit: 1623

= Ph and/or $R^2 = p\text{-OCH}_3$, which also fall within the claimed invention. Therefore the claimed invention is anticipated by Uchida et al.

Response to Argument: Applicant's arguments, submitted February 14, 2008, with respect to the above ground of rejection, have been fully considered and not found persuasive to remove the rejection. Applicant argues that R_2 and R_3 in claim 26 cannot be hydrogen as required by the compounds of Uchida et al. However, Applicant has amended claim 26 to clearly and unambiguously state that when any R group is C_0 alkyl, no alkyl group is present. The absence of an alkyl group, or of any other group, is seen, consistent with the chemical art, to indicate the presence of a hydrogen. Thus these two positions can be hydrogen in claim 26. Therefore the rejection is deemed proper and made **FINAL**.

Conclusion

Claim 26 is rejected. Claims 4 and 25 are seen to be allowable.

Reasons for the indication of allowable subject matter are as follows:

The subject matter of claims 4 and 25 is seen to be adequately enabled and supported under 35 USC 112 by the specification as originally filed. For example, the examples on pp. 30-88 disclose the claimed compounds and how to make them. One of ordinary skill in the art would also know that these compounds are useful drugs for the treatment of nociceptive and neuropathic pain, and for epilepsy, based on the alpha-2-delta ligand activity disclosed on pp 89-148 of the specification, and by analogy with known alpha-2-delta ligands such as gabapentin.

Furthermore the claimed compounds are not seen to be taught or fairly suggested by the prior art. Although pyrrolo-pyridazines have been synthesized in the prior art, for example those of Uchida et al., none of the compounds of claims 4 and 25 are taught in the prior art. Furthermore, there would be no motivation for one skilled in the art to modify them to arrive at the claimed invention as they are not disclosed to have any biological activity or therapeutic utility.

Therefore claims 4 and 25 are seen to be allowable over the prior art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

Art Unit: 1623

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/

Examiner, Art Unit 1623

6/24/2008

/Shaojia Anna Jiang, Ph.D./

Supervisory Patent Examiner, Art Unit 1623